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INTRODUCTION:

Prostate cancer has a huge and growing burden of disease, yet its natural history has not been fully elucidated. Further, it is unknown why African-American men have the highest incidence rates in the world. The **overall goals of the ProCEED pilot study** are: 1) to advance the understanding of the IGF axis and its interplay with race/genetics and dietary/lifestyle risk factors for prostate cancer, 2) To elucidate modifiable risk factors which interact with genetics and possibly lead to a greater incidence of prostate cancer among African-Americans, and 3) to disseminate learned information in an effort to prevent disease. It is hypothesized that racial differences in prostate cancer risk are attributed, in part, to interactions between lifestyle factors and the IGF axis. This study attempts to elucidate dietary and lifestyle risk factors which may operate/interact uniquely in African Americans. If there are lifestyle risk factors for prostate cancer which can be modified, this would be valuable information for primary and perhaps secondary prevention of prostate cancer.

BODY:

The fourth year of the grant was dedicated to the completion of subject enrollment and the beginning of the data analysis phase of the project. At the end of the enrollment period there were 87 subjects enrolled into the study (57 prostate cancer cases and 30 controls). A no-cost extension has been requested in order to process the lab samples and finish the study in 2010. Data management activities, dietary data analysis, laboratory sample processing, and study data entry are currently underway. No final results from this study are yet available.

PUBLICATIONS:

The fourth year of the grant was dedicated to completing subject enrollment in the clinic, and beginning data analysis and thus no new publications were submitted during the reporting period.

FUNDING:

There was no additional funding granted during the reporting period.

RESEARCH ACTIVITIES AND STATEMENT OF WORK:

Below is the approved statement of work with updates and changes described:

Task 1. Identification/recruitment subjects – Ongoing until month 30

As of the end of the reporting period there were 87 subjects enrolled (57 cases and 30 controls). Enrollment commenced in 2009 in order to focus on data management / analysis in 2010.

Task 2. Subject Recruitment and Data Collection, Months 2-29

When patients come in for a 60-minute study visit, the following tasks will take place:

- i. Informed consent*
- ii. Demographic interview*
- iii. Waist/hip circumference and Height/weight measurement*
- iv. Blood sample*
- v. 24-hour dietary recall*
- vi. Work and social history questionnaire*
- vii. IPAQ exercise questionnaire*
- viii. Block Brief food frequency questionnaire*
- ix. Patient incentive given*

In terms of data completeness at study completion, 100% of the subjects had: demographic interviews, height/weight measurements, blood samples, IPAQ exercise questionnaires, and work and social history questionnaires.

Dietary data is still coming in from the subjects (via USPS) but as of 12/29/09 there were 60 of 87 subjects that completed the Block Brief food frequency questionnaire, 57 of 87 subjects that completed at least one 24-hour food recall interview, and 42 of 87 that completed both of the 24-hour food recall interviews. We continue to follow-up with subjects to get as many questionnaires as possible in the final dataset.

Task 3. Determination of serum levels of IGF-1, IGFBP-3, PSA and testosterone, Months 2-29 (for collections and storage), Months 29-31 (for assays and data entry)

As enrollment is now completed, samples will be sent to the central laboratory for processing in mid-January, 2010. Results will be available for statistical analysis 2 weeks after the samples are shipped.

Task 4. Statistical Analyses, Months 30-36

Data is currently being data entered and cleaned. Statistical analysis will be done in mid-to-late January, 2009. A final dissertation report is due by August 2010 to the University of Illinois at Chicago Graduate College in order for Katrine Wallace to participate in the convocation.

KEY RESEARCH ACCOMPLISHMENTS:

- Enrolled 87 subjects into study, completed enrollment during reporting period
- Data cleaning and data management activities completed

REPORTABLE OUTCOMES:

As the third year of the grant was dedicated to subject enrollment, there were no defined reportable outcomes during the reporting period. Manuscripts will be prepared in 2010 after the formal statistical analysis is completed.

CONCLUSIONS:

The third year of the grant was dedicated to completing subject enrollment. A no-cost extension was recently requested in order to complete the data management / analysis in 2010. All results and conclusions will be contained in the 2010 report.